

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 50 percent of the declared amount of vitamin B₁₂.

LIBELED: 12-29-61, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Vit. B-12 60 mcgm." was false and misleading.

DISPOSITION: 1-25-62. Default—destruction.

6935. Liver injection (crude) and Liv-I-Plex injection. (F.D.C. No. 46612. S. Nos. 30-163/4 T.)

QUANTITY: 80 30-cc. vials of *liver injection (crude)* and 104 30-cc. vials of *Liv-I-Plex injection*, at Phoenix, Ariz.

SHIPPED: On 4-26-60 and 11-30-60, from Los Angeles, Calif., by Injectable Pharmacal Co.

LABEL IN PART: (Vial of liver injection) "Sterile Multiple Dose Vial Liver Injection (Crude) USP Each cc. contains Vitamin B₁₂ activity equivalent to 2 micrograms of cyanocobalamin Rocky Mountain Pharmacal Co. Phoenix, Arizona Distributors"; (ctn. of Liv-I-Plex) "Sterile Multiple Dose Vial Liv-I-Plex Fortified Each 2 cc contains: Liver Injection USP 0.1 cc Folic Acid 2 mg. Iron Peptonized 59 mg. Pyridoxine H.C.L. 0.3 mg. Riboflavin 0.3 mg. Sodium Citrate 1% Niacinamide 50 mg. Phenol 0.5% Vitamin B₁₂ Cryst. 30 mcgm. Procaine 1% Distributed by Rocky Mountain Pharmacal Co."; and (vial of Liv-I-Plex) "Sterile Multiple Dose Vial Liv-I-Plex Forte Each cc represents Vitamin B-12 activity (from liver injections, U.S.P. 10 mcgm. per cc) equivalent to: Cyanocobalamin 2 Mcgm. Vitamin B-12 (Crystalline, U.S.P.) 15 Mcgm. Peptonized Iron 20 Mg. Thiamine Hydrochloride, U.S.P. 10 Mg. Riboflavin, U.S.P. 0.5 Mg. Pyridoxine Hydrochloride 1.0 Mg. Panthenol 1.0 Mg. Niacinamide USP 10 Mg. Sodium Citrate, U.S.P. 1.0% Procaine Hydrochloride U.S.P. 0.5% Rocky Mountain Pharmacal Co."

RESULTS OF INVESTIGATION: Analysis showed that the article, *liver injection (crude)*, contained 225 percent of the declared potency of vitamin B₁₂. The National Formulary permits a variation in strength for *liver injection (crude)* up to 150 percent of the potency stated on the label.

The *Liv-I-Plex injection* was in a vial bearing a label which differed from the label on the carton.

LIBELED: 11-9-61, Dist. Ariz.; amended libel 12-1-61.

CHARGE: *Liver injection (crude)*, 501(b)—when shipped, the article purported to be *liver injection (crude)*, a drug, the name of which was recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium since, when assayed in accordance with the method prescribed in the National Formulary, the article contained 225 percent of the potency of its labeled amount of cyanocobalamin; 502(a)—the label statement "Each cc. vitamin B₁₂ activity equivalent to 2 micrograms of cyanocobalamin" was false and misleading as applied to a product containing more than the labeled amount of vitamin B₁₂; and the label statement "Liver Injection (Crude) U.S.P." was false and misleading since the article was recognized in the National Formulary and not in the United States Pharmacopeia, as such label statement represented.

Liv-I-Plex injection, 502(a)—the vial label and the carton label bore statements concerning the composition of the article which were false and mislead-

ing since the composition of the article as declared on the carton label differed in identity and strength from the composition as declared on the vial label.
DISPOSITION: 1-26-62. Default—destruction.

6936. Benat with B₁₂ injection. (F.D.C. No. 46979. S. No. 30-890 T.)

QUANTITY: 333 ctnd. vials at East Los Angeles, Calif.

SHIPPED: 9-1-61, from Philadelphia, Pa.

LABEL IN PART: (Ctn. and vial) "10 ML. Multiple Dose Vial Benat With B₁₂ For Intramuscular Injection * * * Each ML. Contains: * * * Thiamine HCl 10 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 75 percent of the declared amount of thiamine hydrochloride.

LIBELED: 1-12-62, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Each ML. contains * * * Thiamine HCl 10 mg." was false and misleading.

DISPOSITION: 2-9-62. Default—destruction.

6937. Li-Fo-B-12. (F.D.C. No. 46928. S. No. 215 T.)

QUANTITY: 52 ctnd. vials at Miami, Fla.

SHIPPED: 4-26-61, from New Rochelle, N.Y.

LABEL IN PART: (Ctn. and vial) "10 cc. Multiple Dose Vial Li-Fo-B-12 Each cc. contains * * * Vitamin B₁₂ U.S.P. Crystalline 30 mcg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 25 percent of the declared amount of vitamin B₁₂.

LIBELED: 1-22-62, S. Dist. Fla.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Each cc. contains * * * Vitamin B₁₂ U.S.P. Crystalline 30 mcg." was false and misleading.

DISPOSITION: 2-28-62. Default—destruction.

6938. Pas-C powder. (F.D.C. No. 46642. S. No. 13-302 T.)

QUANTITY: 2 50-lb. drums at Chicago, Ill.

SHIPPED: 4-17-61, from New York, N.Y., by Hexagon Laboratories.

RESULTS OF INVESTIGATION: Analysis showed that the article was para-aminosalicylic acid and not para-aminosalicylic ascorbate as represented.

LIBELED: 11-17-61, N. Dist. Ill.

CHARGE: 501(d)(2)—when shipped, para-aminosalicylic acid had been substituted for para-aminosalicylic ascorbate; 502(a)—the label statement "PAS-C" was false and misleading when applied to an article which contained no ascorbic acid (vitamin C).

DISPOSITION: 3-5-62. Consent—claimed by Hellwig, Inc., Chicago, Ill., without admitting the allegations of adulteration and misbranding, and relabeled.

6939. Ergonovine maleate tablets. (F.D.C. No. 46900. S. Nos. 79-384 R, 4-390 T.)

QUANTITY: 1 bulk drum of 5,910 tablets at Huntington, W. Va.